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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/495,556 02/01/00 KUHRTS

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JAMES W. COLLETT, PH.D.
SHELDON & MAK
225 SOUTH LAKE AVENUE
9TH FLOOR
PASADENA CA 91101

HM12/0702

EXAMINER

DI NOLA BARON, I

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

07/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/495,556	Applicant(s) KUHRIS, ERIC H.	
	Examiner Liliana Di Nola-Baron	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner acknowledges receipt of Applicant's amendment, filed on May 14, 2001.

The claimed invention refers to a pharmaceutical composition, comprising a therapeutic agent and an oil, and a method of making encapsulated particles, comprising dispersing a core material in a mixer while adding an oil.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 33, 34, 41, 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
3. The amendment introducing new claims 33, 34, 41, 44 and 45, changing the method to a method without milling or without using a microwave, wherein the mixer does not comprise a chopper, represents a departure from the specification and the claims as originally filed, and Applicant has not pointed where the support comes from. In particular, claims 33 and 44, claiming a composition or a method, wherein the mixer does not comprise a chopper, are in sharp contrast with the disclosure of the invention, which calls for high speed impact choppers to enhance mixing (See e.g., p. 7 and Example 1).

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 30-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "compound" in claims 30-39 is used by the claims to mean "pharmaceutical composition," while the accepted meaning is "chemical substance."

7. Claims 30-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Regarding claims 30-50, the phrase "above about" renders the claim(s) indefinite because the claims include elements not actually disclosed (those encompassed by "about"), thereby rendering the scope of the claims unascertainable.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. Miller et al. discloses a process for manufacturing sustained release particles and dosage forms obtained by processing said particles (See e.g., col. 1, lines 8-15). Miller et al. teaches that the process of the invention comprises working in a high-speed mixer a mixture of a drug, a carrier having a melting point between 35° and 150° C and optionally a release control component, at a speed and energy input, which allows the carrier to melt or soften, and breaking down the agglomerates (See e.g., col. 1, lines 48-67 and Examples 1-4). Miller et al. teaches that the drug may be water soluble or water insoluble, that water soluble drugs are used in amounts up to 90% w/w in the particles of the invention, and water insoluble drugs may be used in higher amounts, up to 99% w/w of the particles, and includes analgesics, such as acetyl salicylic acid, antiallergics, antihypertensives, antibiotics and others among the active ingredients, which can be used in the process of the invention (See e.g., col. 2, line 11 to col. 3, line 28). Miller et al. teaches that preferably all the drug is added, together with the carrier, in the first step, which may be carried out in conventional high speed mixers at temperatures above 40° C (See e.g., col. 3, line 54 to col. 4, line 6). Miller et al. teaches that the agglomerates formed upon heating are allowed to cool and then broken down (See e.g., col. 4, lines 11-25). Miller et al. teaches that the energy in the high speed mixer can be delivered by a heating jacket and the resulting particles may be used to prepare dosage units, such as tablets or capsules (See e.g., col. 4, lines 41-51). Miller et al. teaches that suitable hydrophobic carriers are natural or synthetic waxes or oils, such as hydrogenated vegetable oil, having melting points of 35° –150° C (See e.g., col. 5, lines 15-20). Additionally, Miller et al. teaches that optionally added release control components may be inorganic and organic materials, including calcium and lactose (See e.g., col. 5, lines 27-34).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process and compositions disclosed by Miller et al., by varying the amount of oil, sugar or mineral in the melt and the speed of mixing, to obtain different sustained-release profiles. Because of the teachings of Miller et al., that suitable selection of the materials used in forming the particles and the proportions in which they are used enables a significant degree of control in the dissolution and release rate, one of ordinary skill in the art would have a reasonable expectation that the process and compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

11. Applicant's arguments filed on May 14, 2001 have been fully considered but they have been found only partially persuasive.

12. In response to Applicant's argument, that only claims 1-27 were rejected in the previous Office action, it is noted that the last of the originally filed claims was erroneously numbered 27 instead of 29. Therefore, all claims were rejected in the previous Office action.

13. In response to Applicant's argument, that the prior art (Miller et al.) does not teach a composition or a method, comprising an active agent in an amount of at least 80%, it is noted that Miller et al. teaches that water soluble drugs may be used in amounts up to 90% w/w in the particles of the invention, and water insoluble drugs may be used in higher amounts, up to 99% w/w of the particles (See e.g., col. 2, lines 11-15).

14. In response to Applicant's argument, that the prior art (Miller et al.) does not teach mixing at the speed claimed in the instant application, it is noted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process and compositions disclosed by Miller et al., by varying the speed of mixing to obtain the desired particles.

15. The 35 U.S.C. 103(a) rejection over Oshlack et al. has been withdrawn.

Conclusion

16. Claims 30-50 are rejected.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

June 28, 2001


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600